REMARKS/ARGUMENTS

Status of the Claims

Claims 1-3, 7, 10-18, 28-32, and 34-39 are pending in the present application. Reconsideration and withdrawal of the rejection is respectfully requested in view of the following remarks.

The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

The Examiner has maintained the rejection of claims 1-3, 7, 10-18, 28, 29, 32, 34, 35, and 37-39 under 35 U.S.C. § 112, first paragraph, on the grounds that they lack a sufficient written description. The rejection is respectfully traversed for the reasons described below.

The Examiner argues that the specification does not provide a sufficient written description of the claimed sequence variants and fragments of the *Bt* toxin shown in SEQ ID NO:1, because the specification provides only one working example of a sequence falling within the claimed genus of sequence variants. The Examiner suggests that additional working examples of sequences falling within the claimed genera of sequences would be required to provide a written description of the claimed genera of sequences. However, the *per se* requirement for multiple working examples as applied in the Office Action is not supported by the requirements of 35 U.S.C. § 112, first paragraph, or the applicable case law.

In the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description," 66 Fed. Reg. 1099 (Jan. 5, 2001), the USPTO stated that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant, identifying characteristics, *i.e.* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of these characteristics." *Id.* at 1106. In *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.2d 926 (Fed. Cir. 2002), the Federal Circuit adopted this standard for written description, stating:

> [U]nder the Guidelines, the written description requirement would be met . . . if the functional characteristic of [a genus of nucleic acid molecules] were coupled with a disclosed correlation between that function and a structure that is

> sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement."

The claims of the present application meet the requirements set forth by the Federal Circuit in *Enzo*. As noted in the applicants' previous responses, the specification provides guidance regarding the functional domains of the novel ECB *Bt* toxin receptor, including the toxin binding site and the transmembrane domain, in Figure 1 and on lines 5-10 of page 35 The specification also provides examples of assays for *Bt* toxin binding activity on lines 20-29 of page 5. Accordingly, the present application provides a sufficient written description of the recited variants and fragments of the *Bt* receptor sequence shown in SEQ ID NO:1 because the claims provide the relevant, identifying characteristics, including the partial structure and functional characteristics, of the claimed polypeptides. Claims 1(f), 7(f), and 32 encompass only those polypeptides that contain a ligand binding site having the specified sequence and have *Bt* toxin binding activity. Similarly, claims 1(b)-(e), 7(b)-(e), 28, 29, 34, and 37-90 encompass only those sequences having a designated level of sequence identity with the disclosed *ECB Bt* toxin receptor sequence, where the encoded receptor has *Bt* toxin binding activity.

In the response mailed November 10, 2004, Applicants cited two decisions from the Board of Patent Appeals and Interferences (*Ex Parte Sun*, 2003-1993 (Bd. Pat. App. Int., Jan. 20, 2004) and *Ex Parte* Vogelstein, 2002-0779 (Bd. Pat. App. Int., Dec. 30, 2002)) to exemplify how the Board analyzes the requirements of 35 U.S.C. § 112, first paragraph, as applied to genera of nucleic acid molecules. On page 4 of the Office Action mailed January 31, 2005, the Examiner argues that the decisions in *Ex Parte Sun* and *Ex Parte Vogelstein* are not binding precedent and therefore the analysis followed by the Board in these decisions need not be followed in the present case. However, these Board decisions are persuasive authority that should properly be considered by USPTO examiners when analyzing the written description requirement in factually analogous cases.

The facts of the present case are highly analogous with those in the two Board decisions cited by the applicants. For example, in *Ex parte Sun*, the Examiner had rejected claims directed

to sequences having 80% identity with a novel maize protein tyrosine kinase (Wee1) on the grounds that the specification did not provide a sufficient written description or an enabling disclosure for these variants. The Board reversed the Examiner on both rejections, noting that the specification provided the polypeptide and polynucleotide sequence of the novel kinase and provided assays for screening for the activity of the protein.

The Board stated:

> [T]o satisfy the written description requirement it is not necessary that the application describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure the appellants invented the claimed subject matter. Thus, we do not find the fact that the specification does not specifically teach the structure of a species with 80% identity and Wee1 function to be dispositive of the issue here.

Ex Parte Sun, 2003-1993 at 8. Instead, the Board focused on the fact that the specification disclosed the chemical structure of a polynucleotide that encodes the WEE1 polypeptide, and provided an example of how to screen for WEE1 activity. The Board stated, "[c]ontrary to the examiner's position, it would reasonably appear that such a description in the specification would constitute sufficiently detailed, relevant identifying characteristics of the claimed subject matter consistent with *Enzo*." *Id.* at 9. The Board noted that those of skill in the art knew the domains of the *S. pombe* homolog of WEE1 contained the kinase and substrate-binding activities, and as a result, "those of ordinary skill in the art would have recognized from reading the disclosure that the inventors had invented the isolated Wee1 having the specific nucleotide and amino acid sequences and variations of these sequences with mutations in described specific areas of Wee1, while avoiding the introduction of mutations in other regions." *Id.* at 10.

Similarly, the specification of the present application discloses a nucleotide sequence encoding a novel *Bt* toxin receptor, and the sequence of the encoded polypeptide. As in *Ex parte Sun*, the specification provides examples of assays that may be used to determine *Bt* toxin binding activity. In addition, the specification teaches the domain of the disclosed *Bt* toxin receptor that is required for toxin binding, and the identification of this domain is supported by the Rule 132 declaration of Dr. Cao Guo Yu submitted with the Request for Continued Examination on November 10, 2004. Accordingly, one of ordinary skill in the art would have

recognized from reading the present disclosure that the inventors had invented the isolated *Bt* toxin receptor having the specific nucleotide and amino acid sequences and variations of these sequences. As a result, the present claims meet the requirements for written description under 35 U.S.C. § 112, first paragraph.

In view of the above remarks, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

The Objection to the Claims Should be Withdrawn

Claims 30, 31, and 36 have been objected to on the grounds that they depend from a rejected base claim. It is respectfully submitted that the objection should be withdrawn in view of the fact that Applicants have demonstrated the patentability of claims 1 and 34.

CONCLUSIONS

It is believed that all the rejections have been obviated or overcome and the claims are in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Kathryn L. Coulter

Kathryn L. Coulter
Registration No. 45,889

Customer No. 29122
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

CERTIFICATE OF EXPRESS MAILING

"Express Mail" Mailing Label Number EV184328440US
Date of Deposit: April 28, 2005
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Nora C. Martinez

Nora C. Martinez